Chapter XVI: Protocol Management

Table of Contents

Protocol Consent Form Management in CRIS

This tutorial summarizes the change in documenting the assignment of a patient to a protocol and a new process for forwarding signed protocol consent documentation to the Medical Record Department (MRD). This change in process impacts all end-users of the CRIS system, as well as staff who have previously completed the NIH/MIS Form 54.

The signature page of the completed protocol consent document (Form 2514-1) must be faxed to the MRD at 301 480-3126 upon completion. The original signed protocol consent document must be filed in the inpatient chart for inpatient admissions and forwarded to the MRD for outpatients for filing in the permanent medical record.

Original protocol consent documents must be printed from the clinical research studies website at the following url: http://www.cc.nih.gov/protocolconsents/

Definition of Terms

Form 54/ATV Form – The Form 54 for requesting admissions, travel and vouchers has been replaced by the Admissions, Travel and Voucher System also known as ATV. The ATV system can be found at http://atv.cc.nih.gov. For additional information about the ATV system, contact admissions at 301 496-3141.

Primary Protocol – The primary reason for the patient visit to the Clinical Center. All orders entered into CRIS will be attributed to this primary protocol unless they are included in a protocol order set. The primary protocol in CRIS will be identified as the 'Visit Reason'.

Secondary Protocol – Ancillary protocols specific to a patient visit or spanning multiple visits. Orders entered in CRIS will not be attributed to secondary protocols unless there is an active protocol order set established for that particular protocol.

Generic Protocol - an emergency protocol designation assigned when a patient presents for admission but has no admissions request (Form 54/ATV). This protocol designation is only valid for 72 hours.

Active Protocol – a protocol in which a patient is actively participating

Active Protocol Status Designations

- Unconfirmed – patient assigned to a protocol, but the Medical Record Department has not received either a faxed copy of the signature page of

a valid, signed protocol consent form (NIH-2514-1) and/or the original, valid protocol consent document.
- Confirmed – medical records has received a faxed copy of the signature page of a valid, signed protocol consent form and/or the original, valid protocol consent document.
- Exemption – patient assigned to designated exemption protocol, or remains on a treatment protocol as a "single patient single use" exemption

Inactive Protocol – a protocol in which a patient is no longer participating or the study has ended.

Inactive Protocol Status Designations

- Removed – an *individual* patient is removed from a protocol because of medical reasons, or because they have completed the protocol, or because they have elected to withdraw from the study.
- Error – the protocol was assigned in error.
- Terminated – protocol completed or ended (e.g. end of study) and *all* patients are removed from the protocol.

Visit Reason – a term in CRIS identifying the primary protocol in the health issues section

Protocol Order Set – a group of orders related to a specific protocol

Onset Date – indicates the actual date the protocol consent document was signed

Entered Date – indicates the date that the consent status was entered and/or updated in the CRIS health issues section of the patient information tab.

Description of the New Process

Placing a New Patient on a Primary Protocol or Changing a Primary Protocol:

1. Complete a Form 54 – now known as an Admissions, Travel and Voucher Request (ATV). This form can be found at http://atv.cc.nih.gov
2. Electronically submit the ATV form to admissions.
3. Admissions will register the patient, assign a medical record number and document the patient's primary protocol number. The primary protocol will display in the CRIS header information for the patient, and under visit reason in the CRIS "Health Issues" section of the "Patient Info" tab.

4. Obtain all required signatures on the last page of the protocol informed consent document (NIH-2514-1)
5. Fax the last page (signature page) of the protocol informed consent to Medical Records at 301 480-3126 as soon as all of the signatures have been obtained.
6. Inpatient Status: File the original protocol consent document in the inpatient chart.
   Outpatient status: Forward the original protocol consent document to the MRD for filing in the permanent medical record.
7. The MRD will update the protocol status and confirm receipt of the consent document in the CRIS under the health issues section of the patient information tab no later than the next business day.
8. For subsequent visits, use the ATV request to change the designation of a primary protocol. NOTE: this will only change the primary protocol for the specified patient. The previous primary protocol will automatically become a secondary protocol. To "inactivate" an existing protocol patient assignment, refer to the section below on "Inactive Protocols".

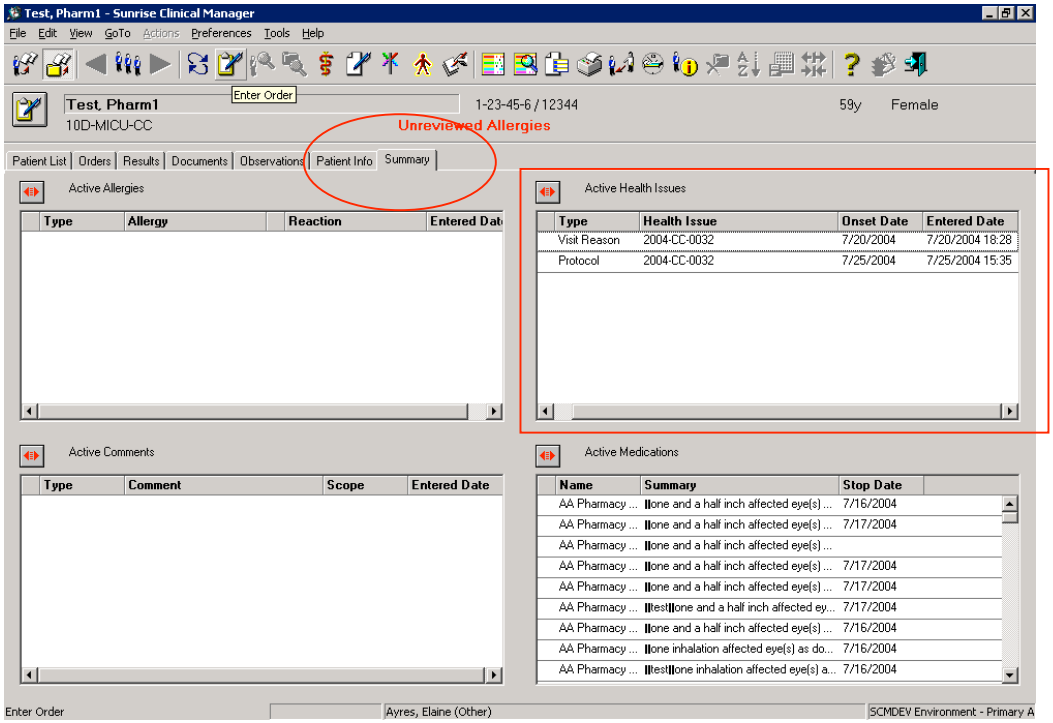
Placing a Patient on a Secondary Protocol:

1. Complete all required signatures on the last page of the protocol informed consent document (NIH-2514-1)
2. Fax the last page (signature page) of the protocol informed consent to the Medical Record Department at 301 480-3126 as soon as all of the signatures have been obtained.
3. Inpatient status: File the original protocol consent form in the in patient chart.
   Outpatient status: Forward the original consent document to the MRD for filing in the permanent medical record.
4. The MRD will update the protocol status and confirm receipt of the faxed signature page of the protocol consent document in the CRIS health issues section of the patient information tab.

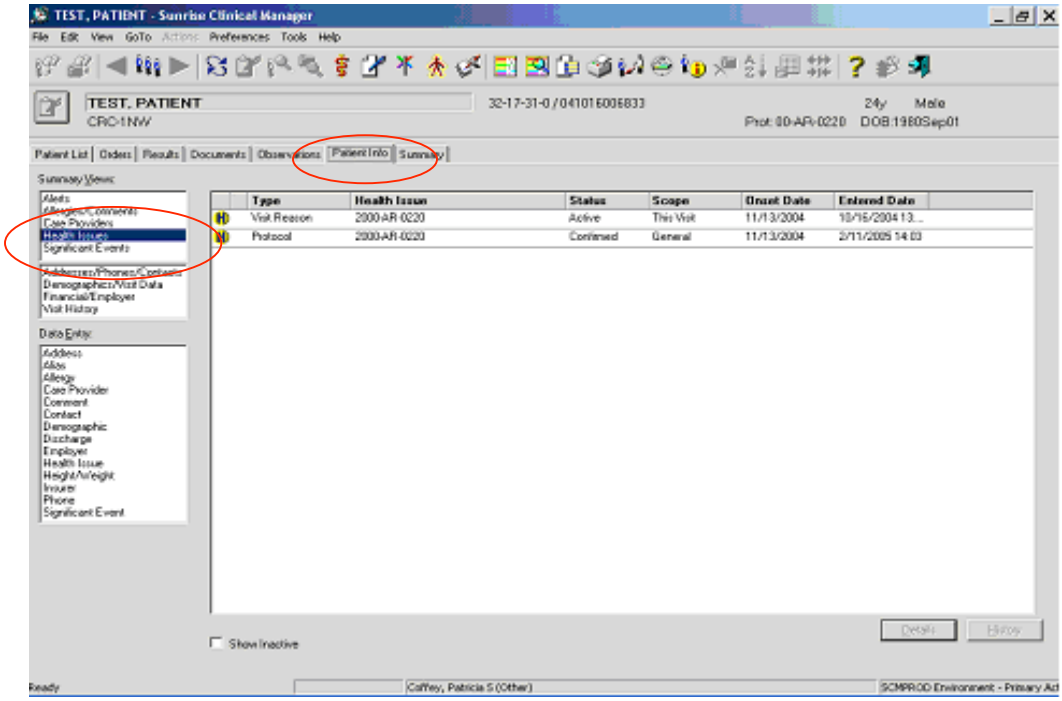
Protocol and Consent Information in CRIS

Viewing Protocol Information, Protocol Status and Consent Form Management in CRIS:

1. Select a patient from the patient list.
2. Protocol information can be viewed under the "Summary" tab under "Active Health Issues".
3. Or the same information can be viewed under the "Patient Info" Tab by selecting the "Health Issues" view.



Screen 1: Sample View of Summary Tab



Screen 2: Sample View of Patient Info Tab

Explanation of Terms on the Health Issues Screen

Type:

Visit Reason – represents the primary protocol. The primary protocol is the reason for the patient visit to the Clinical Center. All orders entered into CRIS will be attributed to this primary protocol unless they are included in a specific protocol order set.

Protocol – represents all other patient protocols, either active or inactive

Health Issues: Lists the protocol number

Status: Designates the status of a protocol for a specific patient.

Active Protocol – a protocol in which a patient is actively participating

Active Protocol Status Designations

- Unconfirmed – patient assigned to a protocol in CRIS, but the Medical Record Department has not received the faxed copy of the signature page from a valid, signed protocol consent form (NIH-2514-1)
- Confirmed – the Medical Records Department has received the faxed copy of the signature page from a valid, signed protocol consent form
- Exemption – will be noted as specific type of exemption by the number assigned:
    - Single Patient Single Use – retains treatment protocol number but protocol status will be noted as "Exemption"
    - Emergency Use IND – Special Exemption Number will be assigned and entered by Medical Records as the Primary Protocol (YR-IC-9980 number)
    - Treatment IND – Special Exemption Number will be assigned and entered by Medical Records as the Primary Protocol (YR-IC-9990 number)

Inactive Protocol – a protocol in which a patient is no longer participating

Inactive Protocol Status Designations

- Removed – an *individual* patient is removed from a protocol because of medical reasons, because they have completed the protocol, or because they have elected to withdraw from the study.
- Error – the protocol was assigned in error.
- Terminated – protocol completed or ended (end of study) and *all* patients are removed from the protocol.

Scope: Indicates "This Visit" for the primary protocol, and "General" for all other protocols

Onset Date: Actual date that protocol consent form was signed.

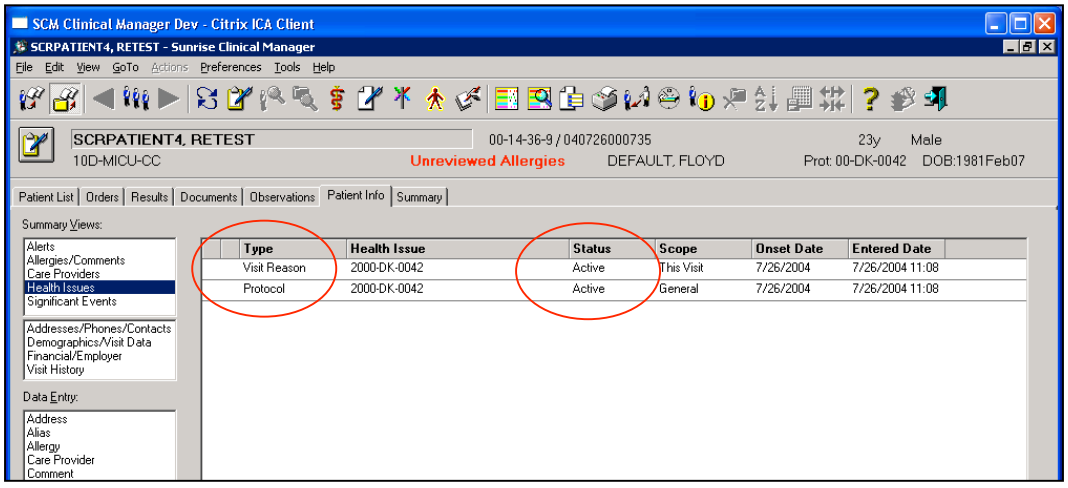
Entered Date: The date that the Medical Record Department entered the consent data into CRIS verifying the receipt of the faxed copy of the protocol consent signature page.

CRIS Documentation of Protocol and Consent Status

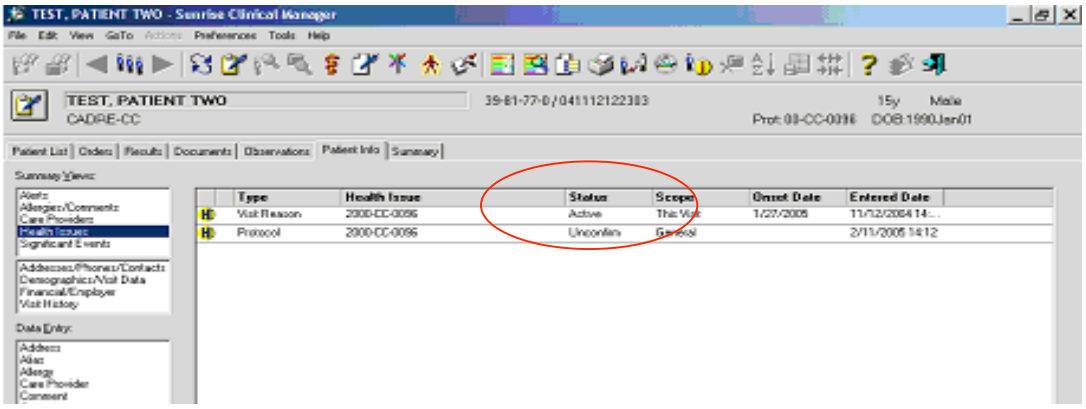
Primary Protocols

A protocol is posted in CRIS when admissions has registered the patient and assigned a patient to a protocol according to the information submitted via the ATV form. The primary protocol is posted twice in CRIS – the "Visit Reason" designates the primary protocol. The "Protocol" will document the consent status.

Prior to the receipt of the faxed copy of the signature page of a valid, signed protocol consent form and/or the original, valid protocol consent document, the MRD will update the protocol status from "Active" to "Unconfirmed" for the protocol.

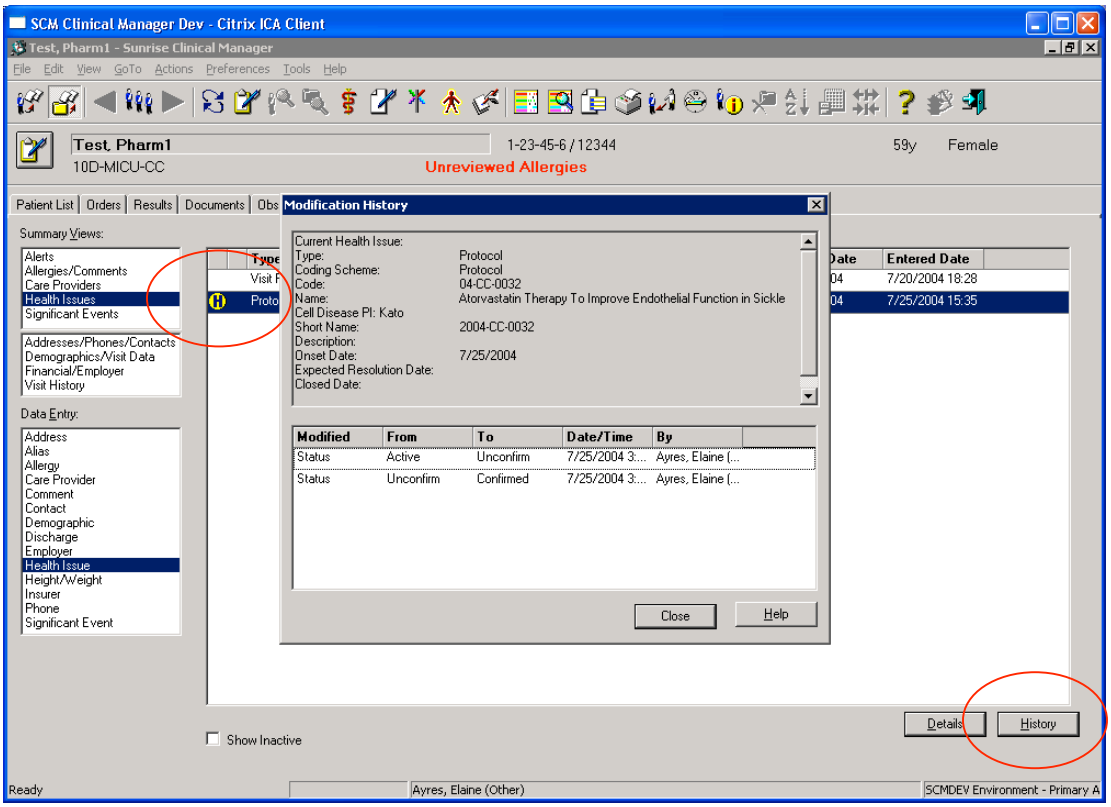


Screen 3: Protocol Visit Types and Status



Screen 4: Change in Status from active to unconfirmed

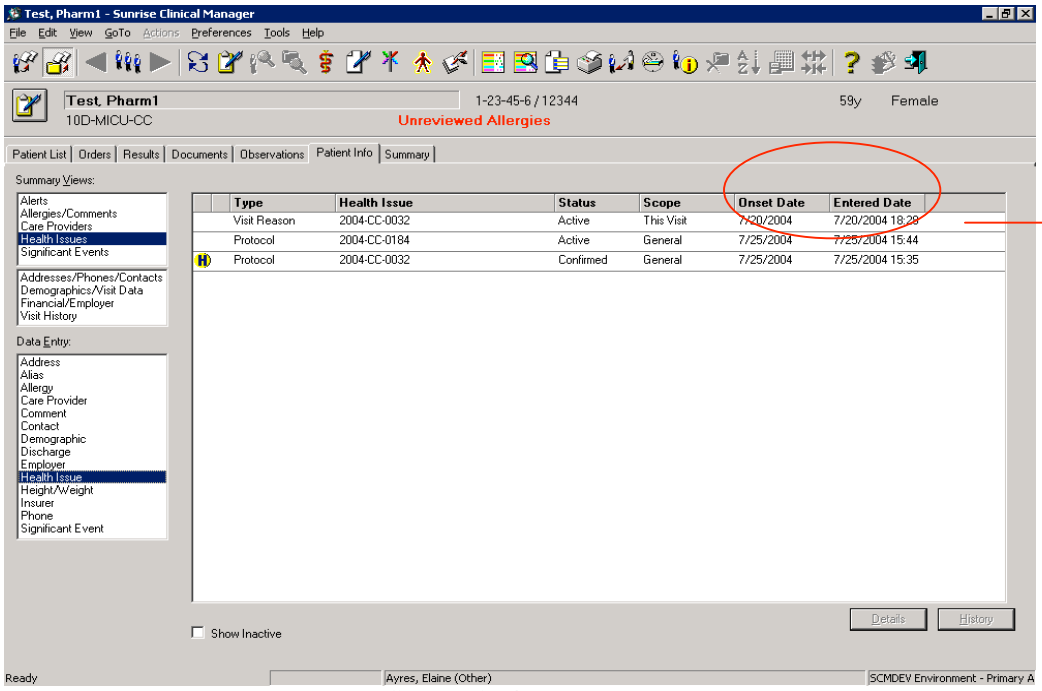
Note the Yellow H next to the protocol. When highlighting a protocol with this "H" icon, the "History" button at the bottom of the screen becomes active. Selecting the History button will display information about the protocol and an audit trail of changes in consent status will appear.



Screen 5: Protocol history display

Placing a Patient on a Secondary Protocol

1. Complete all required signatures and dates on the last page of the protocol informed consent document (NIH-2514-1)
2. Fax the last page (signature page) of the protocol informed consent to the Medical Record Department at 301 480-3126 as soon as all of the signatures have been obtained.
3. Inpatient status: File the original protocol consent form in the inpatient chart.
   Outpatient status: Forward the original consent document to the MRD for filing in the permanent medical record.
4. MRD will update the protocol status and confirm receipt of the faxed signature page of the protocol consent document in the CRIS health issues section of the patient information tab.
5. If a patient changes their primary protocol, the former primary protocol will automatically become a secondary protocol. *(note: I don't believe this is correct. I have never seen this occur, but will follow up with Jon McKeeby to verify—depending on the outcome of that conversation, we may need a new screen shot here)*



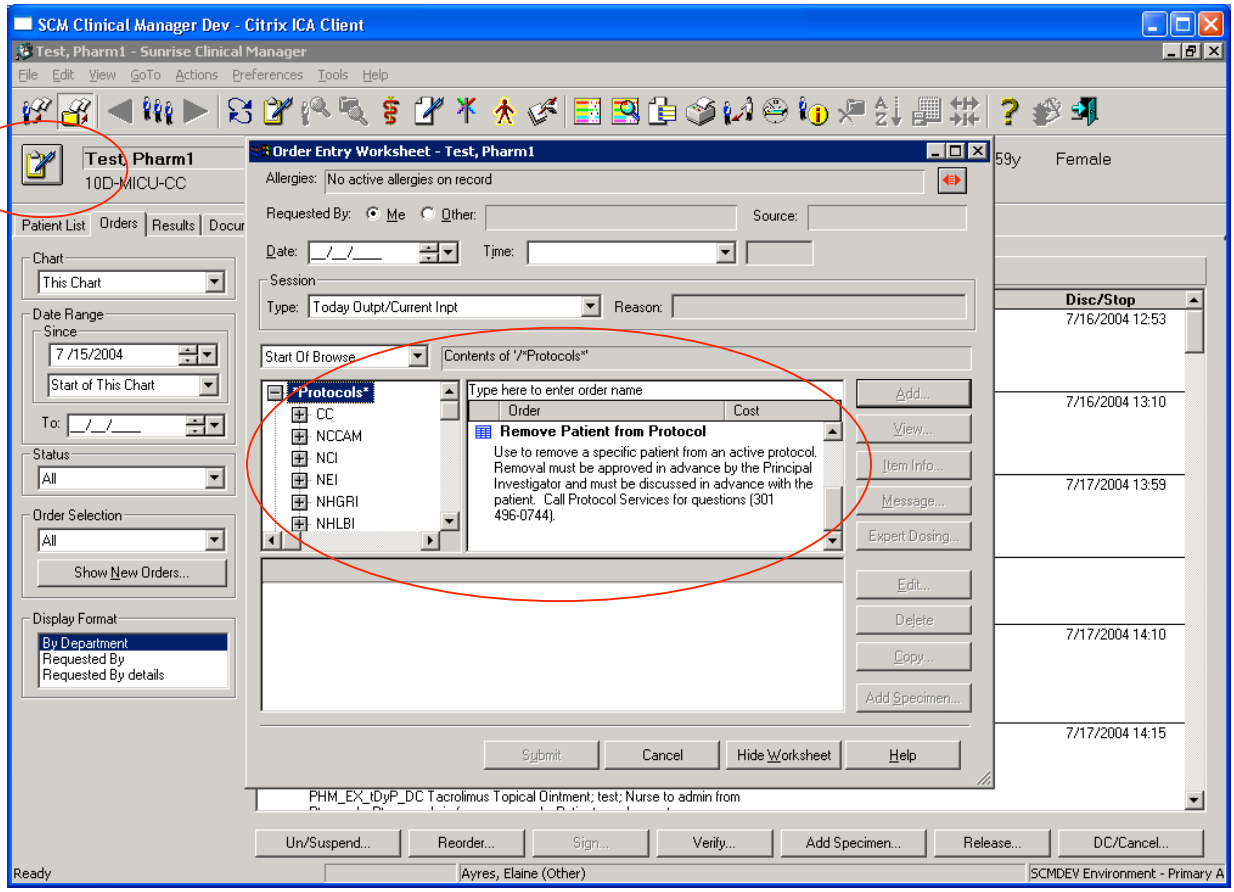
Note addition of new protocol

Screen 6: Onset and entered data

The "Onset Date" indicates the actual date the protocol consent was signed. The "Entered Date" indicates the date that the Medical Record Department entered the consent data into CRIS verifying the receipt of the faxed copy of the protocol consent signature page.

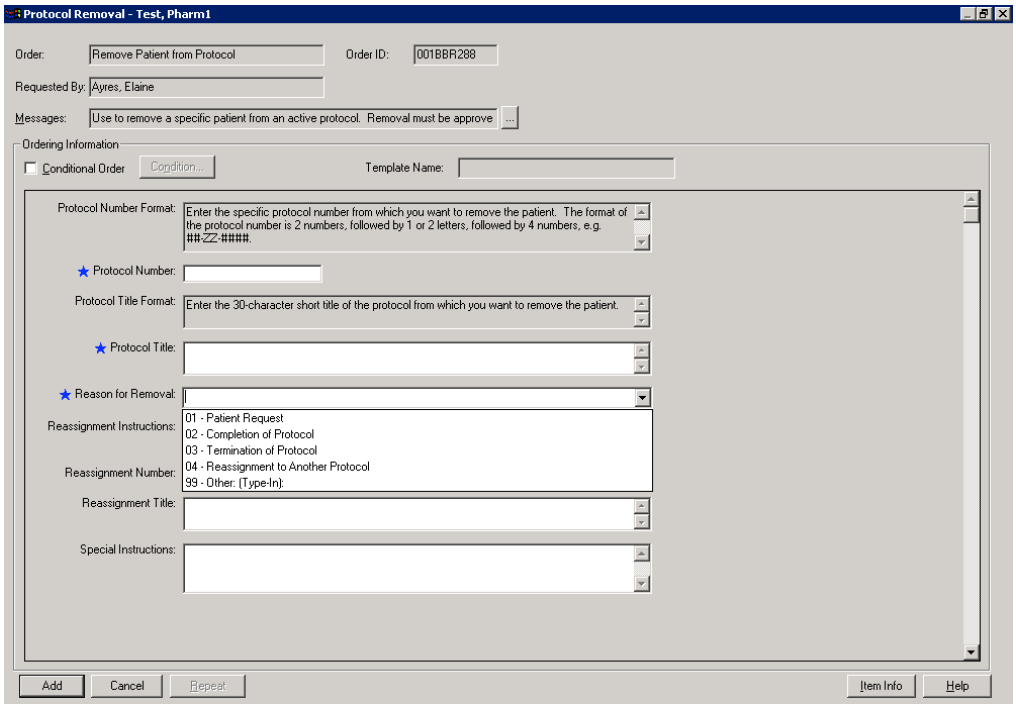
Removing a Patient from a Protocol

1. To remove a patient from a protocol, enter a service request using the Order Entry Worksheet.
2. Make sure a patient selected and click on the Order Entry Icon
3. Expand the protocols order category under Start of Browse
4. Select "Remove Patient from Protocol".



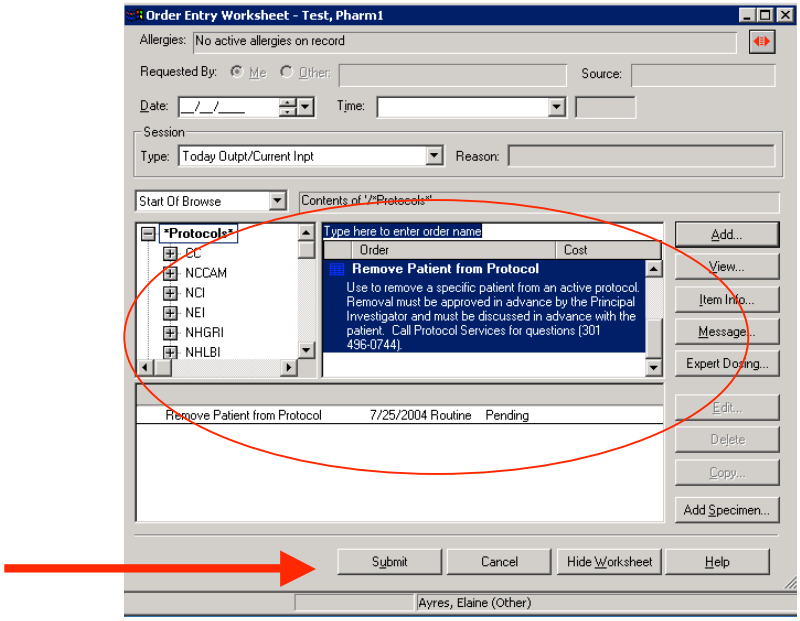
Screen 7: Order entry worksheet display of service requests to remove protocol

5. Within the order form, enter the required information including the current protocol number, the new protocol number (if patient is being reassigned to a different protocol), the protocol title and the reason for removal



Screen 8: Order form

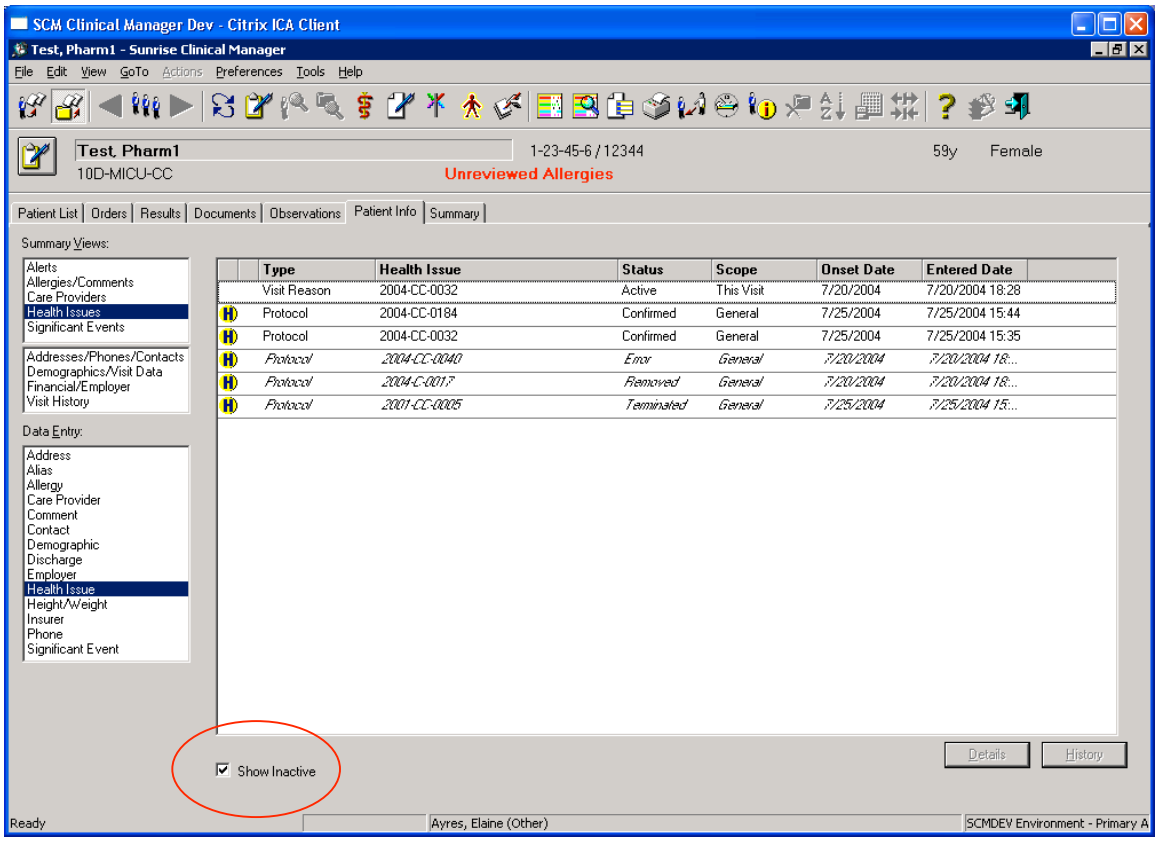
6. Submit the service request. Your request will print as a transmittal in the Medical Record Department. The Medical Record Department will then change the status of the protocol in the health issues section of the patient information tab and that protocol assignment for the selected patient will become inactive.



Screen 9: Submit order

Viewing "Inactive Protocols"

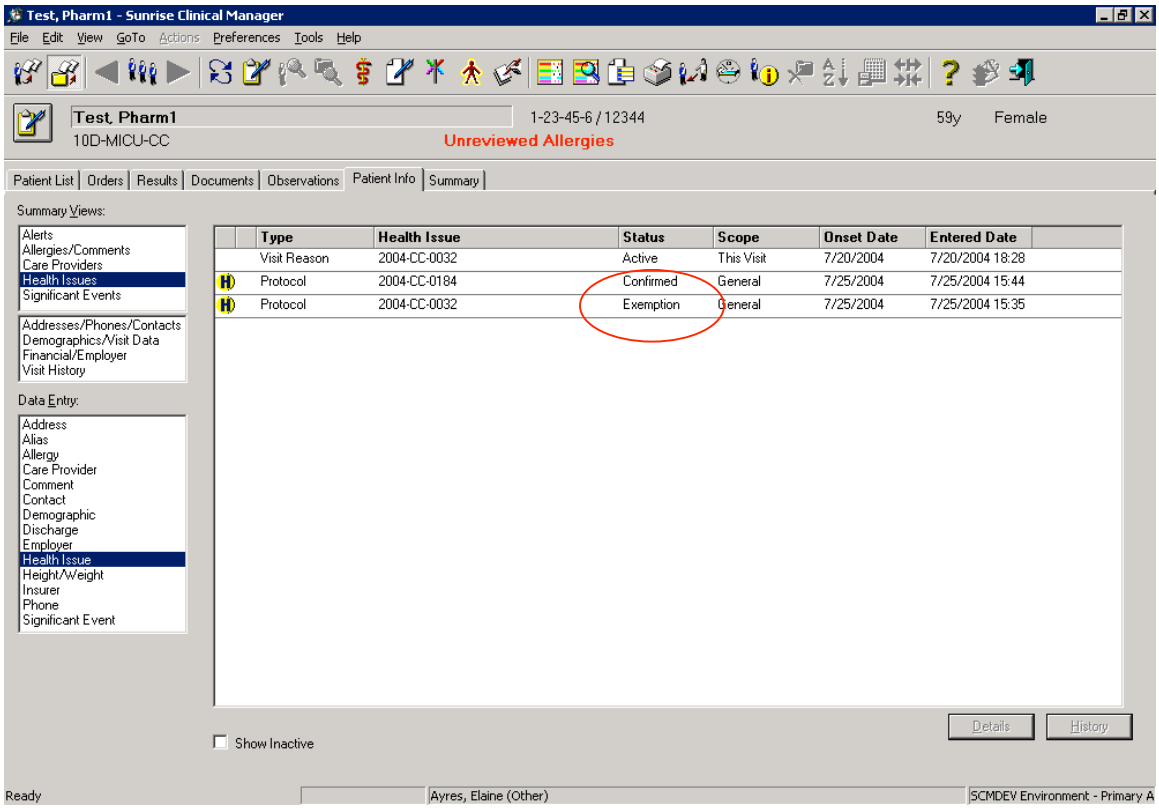
Check the "Show Inactive" box at the bottom left of the patient information screen. Inactive protocols will be added to the display in *italics.* Note that the history is retained for inactive protocols as indicated by the yellow "H" icon.



Screen 10: Inactive status

Placing a patient on a protocol special exemption

The process for placing a patient on a protocol exemption is described in the M93-1 MAS policy on the Structure and Process of Research Involving Human Subjects at the Clinical Center http://internal.cc.nih.gov/policies/PDF/M93-1.pdf. Patients enrolled on special exemptions must be approved by the IC Branch Chief, Clinical Director, IRB Chair and Director of the Clinical Center using the Special Exemption Form (NIH-2702) http://intranet.cc.nih.gov/medicalrecords/forms/pdf/NIH-2702.pdf. Once the paper form is completed Medical Records will post the protocol status in CRIS in the health issues section of the patient information tab.



Screen 11: Exemption status

Protocol and Consent Status Reports

To ensure validity and accuracy of the data on protocols and consent status in CRIS, each Institute will receive end-of-month reports. Reports will be by protocol and will be provided to the Principal Investigator or their designee. Ad hoc reports will be available by request. For additional information on these reports, please call the Medical Record Department at 301 496-2292.